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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,901	07/16/2003	Kevin S. Brandt	FC-8-C3	3345
7590 05/04/2006				
Heska Corporation Intellectual Property Dept 1613 Prospect Parkway Fort Collins, CO 80525			EXAMINER VOGEL, NANCY S	
			ART UNIT 1636	PAPER NUMBER

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/621,901

Applicant(s)

BRANDT ET AL.

Examiner

Nancy T. Vogel

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 6-8 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-8 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1, 2, 6-8 and 18 are pending in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection of record in the previous action not addressed in this office action is withdrawn.

### ***Claim Rejections - 35 USC § 101 and 112***

Claims 1, 2, 6-8 and 18 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 9/16/05. Applicant's arguments filed 12/16/05 have been considered but have not been found convincing.

Applicants have argued that the utility as a genetic vaccine has been provided and that this is a credible, specific and substantial use for flea HMT (Hindgut and Malpighian Tubule) nucleic acid molecules. Applicants argue that US Patent No. 5,766,602 provides sufficient evidence that genetic recombinant vaccines have credible utility. However, US Patent No. 5,766,602 discloses a vector for inserting a gene encoding a protein which when injected into an animal, results in a protective immune response. However, in the instant case, as has been previously argued, there is no evidence submitted that the nucleic acid recited in the claims encodes such a protein.

While it is agreed that genes encoding proteins known to provide a protective immune response may be inserted into vectors and tested for effectiveness, in the instant case, there is no evidence that a specific and substantial utility has been shown for the recited nucleic acid and compositions thereof. Applicant has generally asserted that any gene from the Hindgut and/or Malpighian Tubule of the flea when used in a therapeutic composition, may protect animals from flea infestation. As has been previously argued, this utility is not specific to the claimed nucleic acid. This utility is not substantial since there is no evidence provided that this protection actually occurs with the claimed nucleic acid, as was previously argued. Therefore, the rejection is maintained.

Claims 1, 2, 6-8 and 18 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 102***

Claims 1, 2, 6-8 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Brandt et al. (WO 00/61621).

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 9/16/05, modified slightly to account for amendments made to the claim. Applicant's arguments filed 12/16/05 have been considered but have not been found convincing.

Brandt et al. disclose an isolated nucleic acid molecule having a nucleic acid sequence of SEQ ID NO:26 (see alignment attached to previous Office action, see claim 26, see SEQ ID NO:381, see Table II, page 34). The reference discloses recombinant virus comprising said nucleic acid, and compositions comprising an excipient and said nucleic acid (see page 91).

IT is noted that the recitation of "having a nucleic acid sequence of SEQ ID NO:26" [emphasis added] encompasses nucleic acid molecules having as little as two nucleotides which are contained in SEQ ID NO:26, and therefore, the prior art molecule disclose in WO 00/61621 cited above meets the limitation of the claims. The amendment of "a nucleic acid sequence of SEQ ID NO:26" to "**the** nucleic acid sequence of SEQ ID NO:26" [emphasis added] would be remedial.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

N. Vogel  
4/29/06

  
NANCY VOGEL  
PRIMARY EXAMINER